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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,110	04/05/2001	Elizabeth A. Wang	CIBT-P03-031	7778

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EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/827,110

Applicant(s)

WANG, ELIZABETH A.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 63, 65-68 and 70-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63, 65-68, and 70-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/21/05 has been entered.

Claims 63, 65-68, and 70-75 are pending.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 63, 65-68 and 70-75 are/stand rejected under 35 U.S.C. 102 (a) as being anticipated by Ingham (USPN 5,844,079) for reasons of record which are restated below.

The claimed invention is drawn to a preparation comprising a sonic hedgehog polypeptide sequence in which the polypeptide is formulated for topical application, and which polypeptide is formulated on a sponge, bandage, dressing, or film.

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Ingham et al. teaches topical preparations comprising sonic hedgehog polypeptides encoded by hedgehog related genes, see e.g., for example, column 3. Ingham teaches the Shh polypeptide can comprise a fragment of at least 50, 100 or 150 amino acids in length within the N-terminal half thereof, see, e.g., for example, column 3. In addition, Ingham discloses hedgehog polypeptides which include Shh sequences corresponding approximately to the natural proteolytic fragments of the hedgehog proteins, such as from about Cys-24 through Glu-188, or from about Asn-189 through Ala-475 of the human Shh protein, or analogous fragments thereto, see, e.g., for example, column 3. Ingham discloses methods of introduction of exogenous hedgehog polypeptides at the site of treatment include hydrogels that can be used to form an implant such as within a gauze ( please note that such an implant reads upon one or more of the instantly claimed formulations- e.g., dressing) for sustained release at a particular target site , see e.g., for example, column 52, lines 42-64.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that Ingham fails to teach the particular combination of a post-translationally modified hedgehog polypeptide formulated in a preparation for topical application. However, the examiner contends that Ingham teaches a hedgehog polypeptide which is post-translationally modified (see, e.g., for example, claim 26).

Claims 63, 65-68 and 70-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang (USPN 5,844,079).

Wang discloses a method of administering an agent of hedgehog polypeptides in which the polypeptide is formulated on a bandage, dressing and the like, containing an appropriate

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amount of a hedgehog therapeutic, see, e.g., for example, column 57, lines 55-60 and column 58, lines 21-29.

Therefore, the reference is deemed to anticipate the instant claims above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 63, 65-68 and 70-75 are/stand rejected under 35 U.S.C. 103 (a) as being unpatentable by Ingham (USPN 5,844,079) in view of Wang (USPN 5,844,079).

Based upon the beneficial overall teachings provided by Ingham in view of Wang with respect to hedgehog polypeptides in which the polypeptide is formulated on a bandage, dressing and the like, if not expressly taught, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make result effective adjustments in conventional working parameters thereto (e.g., a topical application of the hedgehog polypeptide formulated on a bandage, dressing and the like) as a mere matter of judicious selection and routine optimization.

Applicant's arguments, as they pertain to Ingham, were carefully considered but were not found persuasive.

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Applicant contends that Ingham fails to teach the benefits of the particular combinations of post-translational modifications, formulations, and mode of administration set forth in the pending claims. Further, applicant contends that the examiner has not provided any evidence that would have motivated one of skill in the art to arrive at applicants' invention. However, the examiner contends that Ingham teaches a hedgehog polypeptide which is post-translationally modified (see, e.g., for example, claim 26). Further, the examiner contends that with respect to hedgehog protein preparation, if not expressly taught, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make result effective adjustments in conventional working parameters thereto (e.g., particular fraction sizes and modifications thereto) as a mere matter of judicious selection and routine optimization.

Claims 63, 65-68, and 70-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (USPN 5,844,079).

Wang discloses a method of administering an agent of hedgehog polypeptides in which the polypeptide is formulated on a bandage, dressing and the like, containing an appropriate amount of a hedgehog therapeutic, see, e.g., for example, column 57, lines 55-60 and column 58, lines 21-29.

Based upon the beneficial overall teachings provided by Wang with respect to hedgehog protein preparation, if not expressly taught, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make result effective adjustments in conventional working parameters thereto (e.g., a polypeptide formulated on a sponge or film) as a mere matter of judicious selection and routine optimization.

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Thus, the claimed invention as a whole is *prima facie* obvious over the cited reference, especially in the absence of evidence to the contrary.

### ***Conclusion***

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER